

REMARKS

In the Office Action mailed September 24, 2002, claims 24-30 were rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (US 5,591,139).

Applicants' invention is a microlancet made of an elongated single crystal silicon substrate that terminates in a sharp point at the penetration end and has a smooth continuous cutting profile for piercing and penetrating the skin.

In contrast, the microneedle described in Lin et al.'s U.S.P 5,591,139 is a complicated affair. While Lin et al. also uses a single crystal silicon layer 46 (e.g., Fig. 1A), that is where the similarity stops. As shown in Fig. 2A and throughout the cross-sections shown in Fig. 3, a heavily-doped region 52 of boron is formed in the upper surface of the silicon wafer to a depth of 12 μm . The boron-doped region is used as an etch stop but at a cost because the heavily-doped boron region has significantly greater levels of internal stress than undoped single crystal silicon. The cross-hatching in Fig. 2A illustrates the boron-doped region and Col. 4, lines 56-59 describe this region as follows: "Boron-doped region 52 defines tip region 84 (FIG. 2A), extends along the needle shaft and defines the perimeter of interface region 11, as best shown in FIG. 2A." Elsewhere, Lin et al. explicitly state that "there is no single crystal silicon at the tip region 86, so that the tip is sharper and smaller than the portion of the shaft including single-crystal silicon" (Col. 4, lines 29-32); and they also explain that "tip region 86 of shaft 14 does not contain any single-crystal silicon due to the corner-etching behavior of EDP [ethyleneidamine pyrocatacol]." (Col. 7, lines 43-44).

Following formation of the boron-doped region, a thin (1 μm) silicon nitride 72 structure is then formed as shown in Figs. 3D through 3G on the upper surface of the silicon layer 46. This structure covers a layer 66 of phosphosilicate glass (PSG) and a layer 68 of low temperature oxide (LTO). Following formation of the silicon nitride structure, the PSG layer 66 and the LTO layer 68 are removed from the interior of the structure by etching in hydrofluoric acid (Col. 6, lines 32-34). What is left is a hollow silicon nitride shell that extends along the shaft of the microneedle. This shell functions as a needle bore that is used as a conduit for fluids (Col. 6, lines 46-52).

The subject matter of the Lin et al. patent is described in the paper, "Silicon Processed Microneedles" that was presented at the 7th International Conference on Solid State Sensors

and Actuators in Yokohama, Japan, June 7-10, 1993. This paper is cited by the applicants at the bottom of page 1 of the specification; and a copy is enclosed for the Examiner's convenience. This paper provides greater detail of the tip structure. Figure 2(b) provides a clearly labeled cross-sectional view of the microneedle that is similar to Figure 2B in U.S. P. 5,591,139. Figure 6 of "Silicon Processed Microneedles" is a scanning electron micrograph of the tip end of the microneedle, clearly showing the end of the boron-doped silicon spine, and the upper two silicon nitride layers forming the tip and the fluid channel.

As is evident in Figure 6, the boron-doped single-crystal silicon terminates before the tip, leaving a silicon-nitride layer that defines the tip. The absence of any single crystal silicon in the tip is also confirmed by a statement nine lines up from the bottom of the left-hand column of text on page 238: "As is evident in Fig. 2(b), no single-crystal silicon is left at the tip region of the microneedle owing to the corner-etching behavior of EDP." (Citation omitted).

Applicants' invention is not anticipated by Lin et al. As described in the specification and as set forth in the claims, applicants' microlancet comprises a single piece of single-crystal silicon.

In contrast, Lin et al.'s needle is complex, consisting of a thin silicon nitride shell supported on a silicon spine. At the penetration end of the needle shaft in the region near the tip, the spine consists of heavily boron-doped silicon only 12 micrometers thick. There is no undoped single-crystal silicon in this region, and the actual tip of Lin et al.'s needle consists of silicon nitride film.

By using a single piece of single crystal silicon, applicants are able to provide a much stronger microlancet and one that can be fabricated much more easily with attendant reductions in assembly time and cost. Applicants avoid altogether the use of the relatively fragile silicon nitride conduit structure of Lin et al. and the elaborate processing steps that are required to form the silicon nitride casing and then etch away the PSG and LTO layers contained therein. Further, applicants avoid the need to form the boron-doped region and the weaknesses this creates in the resulting structure.

Claim 24 has been amended to refer to the sampling of blood and other bodily fluids. The reference to bodily fluids is supported by the specification at page 4, line 33.

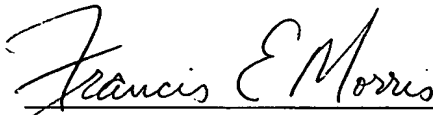
Additional dependent claims 31-34 have been added.

In view of the foregoing, applicants believe that all of the claims are now in condition for allowance and respectfully requests the Examiner to pass the subject application to issue. If for any reason the Examiner believes any of the claims are not in condition for allowance, he is encouraged to phone the undersigned at (650) 849-7777 so that any remaining issues may be resolved.

No additional fee is believed due for filing this response. However, if a fee is due, please charge such fee to Pennie & Edmonds LLP's Deposit Account No. 16-1150.

Respectfully submitted,

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APPENDIX A

Changes to the Specification

The top of page 1 is revised as follows:

SILICON MICROLANCET DEVICE

GOVERNMENT RIGHTS

The United States Government has certain rights in this invention pursuant to Contract No. DAAH01-97-C-R113 awarded by the Defense Advanced Research Agency.

The paragraph at page 7 line 22 to page 8 line 3, is revised as follows:

As illustrated in FIG. 1E, the uncovered areas of the silicon wafer **12e** are etched away in bulk by potassium hydroxide (KOH). Etching the silicon wafer **12e** with potassium hydroxide results in between approximately 50 micrometers and approximately 100 micrometers of the silicon wafer **12e** being exposed. The remaining photoresist **16d** is also removed as illustrated in **FIG. 1F**. Next, as illustrated in **FIG. 1G**, a photoresist coating **18g** is applied to the silicon wafer **12g**. Then, as illustrated in **FIG. 1H**, the silicon wafer **12h** is patterned and exposed and the lancet devices **10h** are “punched” out using a plasma etching process. Plasma etching provides excellent control of the shape of the microlancet without forming weak spots. Finally, as illustrated in **FIG. 1I**, the photoresist coating **18h** is removed resulting in a silicon lancet device with a nitride-covered base.

APPENDIX B

Changes to the Claims

Please amend the claims as follows:

24. (Amended) A microlancet device for obtaining a [blood] sample of blood or other bodily fluid through the skin of a subject, comprising;
- an elongated single crystal silicon substrate having a base end and a penetration end;
 - a base portion formed at the base end of the silicon substrate for permitting the device to be retained during penetration and sampling; and
 - a penetration portion formed at the penetration end of the silicon substrate, terminating in a sharp point with smooth continuous cutting profile for easily piercing and penetrating the skin of the subject in order to obtain a [blood] sample of blood or other bodily fluid while inflicting minimum pain on the subject.
31. (New) The device of Claim 25, wherein the width cross-section dimension of the penetration portion terminates in a chisel-shaped point at the penetration end.
32. (New) The device of Claim 24 wherein the penetration portion has a width cross-section that tapers from a larger cross-section dimension at the base end toward a smaller cross-section dimension at the penetration end.
33. (New) The device of Claim 32 wherein the width cross-section dimension of the penetration portion extends from about 250 micrometers to about 50 micrometers, excluding the sharp point.
34. (New) The device of Claim 24 wherein the penetration portion has a thickness cross-section dimension from about 50 micrometers to about 250 micrometers.